REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 56-63, 65-73 and 76-79 are pending in the present application. Claim 56 has been amended to recite a preparation suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss. In addition, the long chain polyunsaturated fatty acid fraction has been further characterized.

Likewise, claim 73 has been amended to recite a method for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss. Claim 73 has also been amended to further characterize the long chain polyunsaturated fatty acids. Support for the changes to the claims may be found at page 6, line 29 to page 7, line 2 and page 11, line 18 of the present specification.

New claims 76-79 have been added. Support for new claims 76-79 may be found in the present specification at page 11, lines 16-26; page 8, lines 26-27; and page 7, line 19.

In the outstanding Official Action, claims 56-72 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. Applicants believe the present amendment obviates this rejection.

In imposing the rejection, the Official Action alleges that the present disclosure does not enable a preparation suitable for the "prevention" of dementia syndromes, cognitive degeneration or hearing loss. While applicants do not disclaim any potential applications for the claimed composition, applicants note that the term "prevention" has been deleted from claim 56. Rather, claim 56 recites a preparation suitable for treating a mammal having or at risk of developing dementia syndromes, cognitive degeneration or hearing loss.

As a result, applicants believe that the present amendment obviates this rejection.

Claim 66 was rejected under 35 USC §112, second paragraph, for allegedly being indefinite. Applicants believe the present amendment obviates this rejection.

Claim 66 was rejected for allegedly being vague and indefinite because it was unclear to the Patent Office whether fraction c) comprised copper and zinc. However, claim 66 has been amended to show that fraction c) comprises zinc and that the preparation further comprises copper. As a result, applicants believe that claim 66 is definite to one of ordinary skill in the art.

Claims 56, 59-62, 65, 69-70, and 72 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN 4,810,497, DELLA VALLE et al. 4,595,680 and FUGH-BERMAN et al. This rejection is respectfully traversed.

In imposing the rejection, applicants believe that the Examiner uses an improper analysis for determining a *prima facie* case of obviousness. The Examiner is respectfully reminded that to establish a *prima facie* case of obviousness, three basic criteria must be met.

First, there must be some suggestion or motivation, either in the publications themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a publication. Second, there must be a reasonable expectation of success. Third, the publications must teach or suggest all the claim recitations.

The teaching or suggestion to make the claimed invention and the reasonable expectation of success must be found in the publications, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP §2143-2143.03. Upon reviewing the outstanding Official Action, it is believed that the Official Action fails to satisfy these criteria.

Applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fails to provide the necessary motivation and reasonable expectation of success to combine and modify their respective teachings in manner so as to obtain the claimed invention.

In particular, applicants believe that the proposed combination of reference fails to disclose or suggest a

preparation or method treatment that provides the unexpected and improved benefit over previous preparations and methods as set forth in the present invention.

At this time, the Examiner's attention is respectfully directed to the declaration by Laus Broersen attached with this amendment. The declaration reports the results of an in vitro study that examines the effects of fatty acids and phopsholipid supplementation on cholinergic receptor activation. Applicants submit that the declaration shows that the combined supplementation of fatty acids and phospholipids unexpectedly compensate for the loss of acetylcholine in dementia and support normal cognitive functioning in dementia.

The Examiner's attention is also respectfully directed to the by Martijn C. de Wilde filed in the previous response. A copy is attached for the Examiner's convenience. Applicants believe that the experiments set forth in the declaration show that the presently claimed combination of long chain polyunsaturated fatty acids (PUFA), methionine metabolism factors and phospholipids (see supplement 2) exhibit unexpected and improved blood vessel health and improved spatial memory.

As already noted, a 2-vessel occlusion method, a method commonly employed in studies on aging and dementia, is used to compare the effects of the claimed preparation relative to a control diet. Upon reviewing the results, applicants believe that it is clear that essential fatty acids (EFAs) or EFAs

together with polyunsaturated fatty acids (PUFAs) do not restore vascular function in atherosclerosis animal models. Rather, the combination of polyunsaturated fatty acids, vitamins and phospholipids according to the claimed invention, provides markedly improved unexpected benefits over a control diet.

While the Patent Office has taken the position that the declaration is not commensurate in scope with the claimed invention, applicants note that the Patent Office fails to provide any evidence to suggest that the unexpected nature of the claimed invention is not derived form the combination of ingredients, recited amounts, and recited ratios set forth in the claims.

Moreover, as previously noted, HORROBIN describes a long-chain fatty acid composition supplying 20 mg to 10 g of a total amount of EPA + DHA + D(H)GLA + AA relative to the total amount of 2-30 g of LA + ALA (see column 2, lines 55-59). Applicants note that these are amounts substantially lower than those claimed in claims 56 and 73. Moreover, the ratio of this combination is roughly 0.01:1 to 0.33:1, a ratio that is lower than the claimed ratio (e.g., see claim 61). Thus, HORROBIN fails to teach the claimed ratio. Indeed, HORROBIN actually teaches away from the claimed ratio.

In an effort to remedy the deficiencies of HORROBIN, the outstanding Official Action cites to DELLA VALLE et al. However, DELLA VALLE et al. do not teach the claimed amounts nor

ratios of long-chain fatty acids that may be administered to an individual as set forth in the claimed invention. As a result, it is believed that DELLE VALLE fails to provide the necessary motivation and reasonable expectation of success to combine and modify the teachings of HORROBIN and DELLE VALLE in manner so as to provide the claimed invention.

In a further effort to remedy the deficiencies of HORROBIN and DELLA VALLE et al., the Official Action cites to FUGH-BERMAN et al. FUGH-BERMAN et al. teach that DHA and EPA, but not AA and DHGLA, may be added to a dietary supplement. Thus, at best, the teachings of FUGH-BERMAN et al. are speculative in nature. FUGH-BERMAN et al. teach that more research should be conducted before natural products can be administered as psychotherapeutic agents (abstract). Moreover, applicants note that FUGH-BERMAN et al. fail to disclose or suggest the claimed amounts or claimed Ω-3/Ω-6 ratio.

As a result, applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fails to teach the claimed invention.

Once again, the Examiner is respectfully reminded that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of the variable might be characterized as routine experimentation. *In re Antonie* 559, F.2d 618, 195 USPQ 6 (CCPA

1977). As noted above, the cited publications fail to teach the claimed amounts and ratios. In fact, the cited publications teach away from the claimed invention in using amounts contrary to those recited in the claims.

As a result, applicants believe that the cited publications fail to show that any of the claimed amounts and ratios are simply a matter of routine experimentation.

Furthermore, the Examiner is respectfully reminded that a critical step in analyzing obviousness pursuant to 35 U.S.C. §103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, only guided by the publications and then-accepted wisdom in the field. Close adherence to this methodology is important in cases where the invention itself may prompt an Examiner to "fall victim to the insidious effect of a hindsight syndrome, wherein that which only the invention taught is used against its teacher." Indeed, to establish a prima facie case of obviousness, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab,* 217 F.3d 1365, 1369-70, 55 USPQ 2d 1313, 1362 (Fed. Circ. 2000). The fact that the prior art could be so modified would not have made the modification itself obvious unless the cited publications themselves suggested the desirability of the modification. *In re Gordon,* 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Circ. 1984).

As the above-identified publications each fail provide some motivation, suggestion or teaching of the desirability of making the specific combination, claimed amounts and recited rations that was made by the applicant, applicants believe that the proposed combination of references fail to disclose or suggest the claimed invention.

Thus, in view of the above, applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fails to render obvious the claimed invention.

Claims 56-58 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al, FUGH-BERMAN et al. and TAIYO FISHERY CO., LTD. This rejection is respectfully traversed.

Applicants respectfully submit that the TAIYO FISHERY CO., LTD. publication fails to remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. Indeed, the TAIYO FISHERY CO., LTD. publication does not even discuss long-chain fatty acids.

Thus, applicants believe that the proposed combination fails to render obvious the claimed invention.

Claims 63 was rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and YU et al. 5,177,082. This rejection is respectfully traversed.

Applicants note that YU et al. are silent as to long-chain fatty acids. As a result, applicants believe that YU et al. fail to remedy the deficiencies of the above-identified publications.

As a result, applicants believe that the combination of HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and YU et al. does not render obvious the claimed invention.

Claims 64-65 were rejected under 35 USC 103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and SMITH et al. 6,008,221. This rejection is respectfully traversed.

SMITH et al. fail to remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. SMITH et al. neither disclose nor suggest the amounts and ratios as set forth in the claimed invention.

Thus, applicants believe that the proposed combination fails to render obvious claims 64-65.

Claims 65-66 were rejected under 35 USC 103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and HUTTERER 4,837,219. This rejection is respectfully traversed.

HUTTERER fails to disclose or suggest the administration of long-chain fatty acids as set forth in the claimed invention for treating Alzheimer's disease. Moreover, HUTTERER fails to teach any of the claimed amounts and ratios.

Thus, applicants believe that HUTTERER fails to remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al.

Thus, applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and HUTTERER does not teach the claimed invention.

Claims 71 was rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al., SMITH et al., HUTTERER and GLICK 5,004,615. This rejection is respectfully traversed.

While GLICK may teach the administration of dietary supplements for preventing and controlling dementia and memory loss, GLICK fails to disclose or suggest the administration of long-chain fatty acids. Moreover, GLICK does not remedy any of the deficiencies of HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al., SMITH et al. and HUTTERER.

As a result, applicants believe that the proposed combination fails to render obvious the claimed invention.

Claims 67-68 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and RABIEN (DE 4309217). This rejection is respectfully traversed.

While the outstanding Official Action contends that RABIEN teaches a composition comprising alpha lipoic, panthothenic acid and vitamin E for treating Alzheimer's disease,

RABIEN is silent as to the administration of long-chain fatty acids. Moreover, RABIEN fails to disclose or suggest any of the claimed amounts or ratios.

As a result, applicants believe that RABIEN fails to remedy the deficiencies of the above-identified publications and request that the rejection be withdrawn.

At this time, applicants respectfully request that claim 73 be **rejoined** with the preparation claims. As the Examiner is aware, if applicants elect claims directed to the product, and a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following items:

- declaration by Maria Broersen
- declaration under Rule 132 by Martijn C. de Wilde